Comparative study of home ovulation tests, including new dual-hormone test, to reference day of LH surge

S. Johnson, S. Godbert, L.Marriott, R. Evans, S. Hart

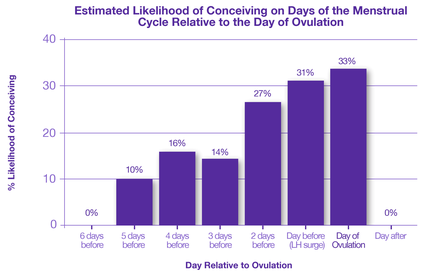
SPD Development Company Ltd., Priory Business Park, Bedford, MK44 3UP, UK

Introduction

- Many women have an inaccurate perception of when they ovulate, even when actively trying to conceive[1]
- Home ovulation tests are a popular and convenient way for women to time intercourse in order to facilitate a natural conception and they can assist with timing of artificial insemination
- A variety of tests are available, which provide either a visual (line) or digital test result; however, it has been demonstrated that 1 in 4 women can interpret line tests incorrectly[2]
- A new dual-hormone test is available that tracks both luteinising hormone (LH) and estrone-3-glucuronide (E3G, a urinary metabolite of estradiol) across a woman's menstrual cycle.

Background to dual-hormone test

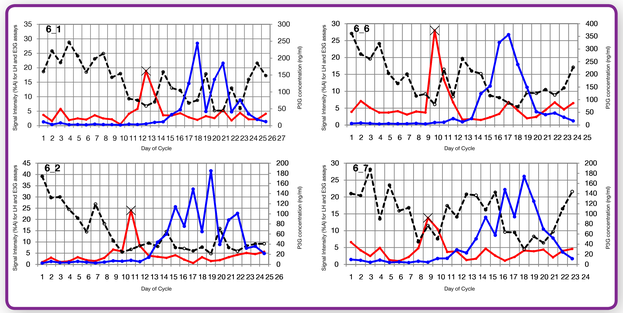
As with other ovulation tests, the dual-hormone test detects the LH surge with ovulation predicted to occur the following day;[3] the test terms these 2 days as PEAK fertility as they are the days when the chances of conception are highest.[4] However, due to the ability of sperm to survive several days in the fertile cervical mucus that is present in the days before ovulation, conception is also possible up to 5 days before ovulation, as shown in the figure below from the study by Wilcox *et al*.[4]



Adapted from data by Wilcox AJ., *et al*, NEJM (1995) 333: 1517

The rise in E3G typically occurs a few days before the LH surge, therefore by tracking this hormone, the new dual-hormone test is able to identify the additional days of HIGH fertility before the LH surge, where conception is possible. This is communicated in the following easy-to-understand format:

The figure below shows the assay signal results from the LH (red line) and E3G (black dotted line) assays in menstrual cycles from a single volunteer. Note, that due to the small size of E3G, a competitive assay is employed, thus the signal decreases as concentration increases. A clear rise in E3G is seen several days before the LH surge. Correct identification of the LH surge is confirmed by the rise in a urinary progesterone metabolite (blue line) after the surge (quantitatively measured by AutoDELFIA).



Objective:

This study aimed to compare the accuracy of six home ovulation tests in detecting the LH surge and the number of days of fertility identified by each test.

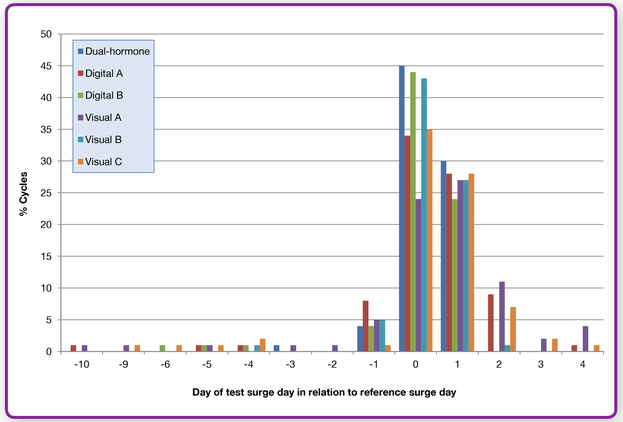
Methods:

Complete menstrual cycles of daily urine samples were tested with two digital (A: First Response, B: Clearblue), three visual (A: First Response, B: Clearblue, C: Answer) and the dual-hormone digital test (Clearblue), in a random order by technicians blinded to the samples. The reference day of LH surge was determined by quantitative measurement of LH by AutoDELFIA. The first day of testing was determined using the information from each tests respective instruction leaflet. Only cycles where a surge was present, as detecting by the reference method (n=87, each from a different woman), were analysed using the home tests.

The architecture of the dual-hormone test, including its internal configuration is shown below.

Results

LH surge detection agreed with the reference surge in 90% of cycles using the dual-hormone test, which matched the highest detection level seen for any of the LH-only ovulation tests included in this study. The accuracy of surge detection, although high for all, varied between tests, as shown in the figure below, with a number of tests indicating a surge too early in some cycles, and several tests detecting the surge after ovulation (Digital A and Visual A and C). The dual-hormone tests gave the most accurate surge detection on the cycles tested.



When the surge was correctly identified, the LH-only home ovulation tests provided the user with information on 2 days where timed intercourse could lead to pregnancy. The dual-hormone test displayed at least two additional days of high fertility prior to the LH surge in 80% of cycles, providing a user with more information on their wider fertile window.

Conclusions

- Home ovulation tests differ in their ability to detect the LH surge
- This study found that the dual-hormone test produced results most in agreement with the reference surge day
- Certain tests detected the surge too late in the cycle, after ovulation, when conception would not have been possible
- The additional high days of fertility identified by the dual-hormone test also offers the added benefit of providing users with greater awareness of their wider fertile window
- This can enable better planning and identifies more opportunities to time intercourse for women hoping to conceive naturally, or could allow effective planning for artificial insemination.

References

1. Zinaman M, *et al* (2012) Curr Med Res Opin 28:749
2. Johnson S, *et al* (2011) Expert Opin Med Diagn. 5:467
3. Behre H, *et al* (2000) Human Reproduction 15:2478
4. Wilcox A, *et al* (1995) NEJM 333:1517

DECLARATION OF INTEREST

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